Designing and Implementing a Quality Management System
Dawn N. Pope, CIP
WIRB-Copernicus Group

Statement of Problem: In 1998, the National Institutes of Health Office of the Inspector General’s report, “IRBs: A Time for Reform” concluded, ”The IRB process is too important not to undergo periodic evaluation. Evaluations can help an IRB to determine whether it is effectively protecting human subjects, whether it is operating efficiently, and whether it has adequate authority (Office of the Inspector General, 1998a, p. 20).” More than a decade later, Lara Abbott and Christine Gradyi published a systematic review of literature evaluating IRBs and concluded that little is about "best practices for enhancing efficiency, for documenting the rationale for their decisions, for justifying variation, for reducing costs, or for measuring IRB quality." Designing and developing a quality management system within the IRB may provide an organization-wide framework to analyze and improve the efficiency and effectiveness of IRB operations.

Description of the Program and Suggestions for Implementation at Other Sites: That’s why, in 2009, our IRB decided to implement ISO 9001:2008 Quality management systems – Requirements—to not only get the job done, but to get the job done better. This presentation (poster) will: Briefly describe the ISO 9001:2008 standard based on eight quality principles; provide guidance on how to develop quality policy and objectives; describe some of the key components of a strong quality management system including controlled standard operating procedures, internal audits, and a systematic a corrective and preventive action program to ensure regulatory compliance, and the continuous improvement of the efficiency and effectiveness of IRB operations. Our IRB reached its goal of attaining ISO 9001:2008 certification in 2010, and was recertified in 2013. Since implementation of a quality management system, our organization saw improvements in three of its key metrics – reduction in errors, turnaround time, and customer satisfaction. Our organization encourages staff to actively participate in the quality management system; and IRB staff are kept informed of results of recent audits, upcoming audits, performance metrics, customer satisfaction results, and other quality improvement initiatives. This initiative sent the message across the organization that quality is no longer solely the responsibility of the Quality Assurance/Quality Improvement team. IRBs who are not interested in ISO certification may still consider adopting standards, principles. and tools to support a quality management systems approach to continuous quality improvement.